# UNITED STATES DISTRICT COURT EASTERN DISTRICT OF NEW YORK JANE DOE on behalf of herself and her minor child, SARAH DOE, Plaintiff, vs. Plaintiff, vs. 2:21-CV-05012 (FB) (SIL) FRANKLIN SQUARE UNION FREE SCHOOL DISTRICT, and MARY T. BASSETT, in her official capacity as Commissioner of the New York State Department of Health, Defendants. Defendants.

# STATE DEFENDANT'S REPLY MEMORANDUM OF LAW IN FURTHER SUPPORT OF HER MOTION TO DISMISS PLAINTIFF'S AMENDED COMPLAINT

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# **TABLE OF CONTENTS**

			Page
I.	Plainti	ff Abandoned Her State Law Claims Against DOH	1
II.	Federa	al Law Does Not Preempt the School Mask Rule	2
III.	Plainti	ff's Substantive Due Process Claims Are Meritless	4
	A.	Plaintiff's Alleged Right to a Medical Exemption	4
	B.	Plaintiff's Alleged Right to Refuse the "Medical Intervention" of Masking	5
	C.	Plaintiff's Alleged Right to Override Public Health Measures Based on Guidance from Her Personal Physician	6
	D.	The School Mask Rule Easily Passes Rational Basis Review	8
IV.	Plainti	ff's Disability Discrimination Claims Against DOH Are Unavailing	9
Conclu	usion		11

# TABLE OF AUTHORITIES

	Page(s)
CASES	
Abdullahi v. Pfizer, Inc., 562 F.3d 163 (2d Cir. 2009)	6
Agudath Israel v. Cuomo, 983 F.3d 620 (2d Cir. 2020)	9
Apotex Inc. v. Acorda Therapeutics, Inc., 823 F.3d 51 (2d Cir. 2016)	3
Ayotte v. Planned Parenthood of N. New England, 546 U.S. 320 (2006)	5
Bare v. Cardinal Health, Inc., 2022 WL 702593 (E.D. Tenn. Mar. 8, 2022)	2
Crosby v. Austin, 2022 WL 603784 (M.D. Fla. March 1, 2022)	2
Dixon v. De Blasio, 2021 WL 4750187 (E.D.N.Y. Oct. 12, 2021) (Cogan, J), vacated and remanded on other grounds, (2d Cir. Mar. 28, 2022)	3
Doe v. Merck & Co., 803 F. App'x 559 (2d Cir.), cert. denied, 141 S. Ct. 900 (2020)	10
Doe v. Zucker, 520 F. Supp. 3d 217 (N.D.N.Y. Feb. 17, 2021)	7
Esperanza v. City of N.Y., 325 F. Supp. 3d 288 (E.D.N.Y. 2018)	1
Gunter v. N. Wasco Ctyu. Sch. Dist., 2021 WL 6063672 (D. Or. Dec. 22, 2021)	5
Hopkins Hawley, LLC v. Cuomo, 518 F. Supp. 3d 705 (S.D.N.Y. Feb. 9, 2021)	9
Jacobson v. Massachusetts, 197 U.S. 11 (1905)	5, 8-9
Johnson v. City of N.Y., 2017 WL 2312924 (S.D.N.Y. May 26, 2017)	1

Maryland v. Wilson, 519 U.S. 408 (1997)	9
PDK Labs v. Friedlander, 103 F.3d 1105 (2d Cir. 1997)	2
Planned Parenthood of Se. Pennsylvania v. Casey, 505 U.S. 833 (1992)	5
Roman Catholic Diocese v. Cuomo, 141 S. Ct. 63 (2020)	8
S. Bay United Pentecostal Church v. Newson, 141 S. Ct. 716 (2021)	9
Sternberg v. Carhart, 530 U.S. 914 (2000)	5
W. Virginia State Bd. of Educ. v. Barnette, 319 U.S. 624 (1943)	7-8
Whalen v. Roe, 429 U.S. 589 (1977)	7
Constitutions	
First Amendment	8
Eleventh Amendment	1
Fourteenth Amendment	8-9
Supremacy Clause	2
FEDERAL STATUTES	
21 U.S.C. § 337(a) § 360bbb-3(e)(1)(A)(ii)	2
42 U.S.C. § 1983	2
Americans with Disabilities Act	10
Federal Food, Drug and Cosmetic Act	2

RULES	
Local Rule 6.3	6
MISCELLANEOUS AUTHORITIES	
https://www.fda.gov/medical-devices/personal-protective-equipment-infection-control/n95-respirators-surgical-masks-face-masks-and-barrier-face-coverings (last visited May 12, 2022)	3

State Defendant Mary T. Bassett, M.D., M.P.H., sued in her official capacity as Commissioner of DOH,<sup>1</sup> respectfully submits this reply memorandum of law in further support of her motion to dismiss the Amended Complaint. Although the School Mask Rule, challenged by Plaintiff in this case, was lifted by State Defendant on March 2, 2022 based on reduced COVID-19 incidence and prevalence in New York State, Plaintiff nonetheless continues to pursue her flawed challenge to its requirements. This action should be dismissed, and DOH's motion granted, because Plaintiff's opposing arguments fail to overcome the manifest deficiencies in her case raised by State Defendant's motion.

### I. Plaintiff Abandoned Her State Law Claims Against DOH

In its moving brief, DOH explained that the State's Eleventh Amendment immunity fully bars Plaintiff's State law claims of purported fundamental rights violations under the State constitution and State common law, and her *ultra vires* claims asserted under the same authorities. DOH Mem. at 11-13. Plaintiff does not address those claims in opposition to DOH's dismissal motion ("Opp."). Thus, she has abandoned them. *Johnson v. City of N.Y.*, 2017 WL 2312924, at \*17 (S.D.N.Y. May 26, 2017) ("By failing to address Defendants' arguments in support of dismissing this claim, it is deemed withdrawn or dismissed as abandoned.") (collecting cases); *Esperanza v. City of N.Y.*, 325 F. Supp. 3d 288, 298 (E.D.N.Y. 2018) (plaintiffs "abandon[ed] the remainder of their claims" "by failing to offer any opposition").

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<sup>&</sup>lt;sup>1</sup> The State Defendant uses the same defined terms as set forth in her memorandum of law in support of her motion to dismiss the Amended Complaint, dated February 25, 2022 ("DOH Mem.").

<sup>&</sup>lt;sup>2</sup> Plaintiff attempts to defend her NYSHRL claims (Opp. at 32-22), but those claims were asserted only against the District. Am. Compl. ¶ 315.

Plaintiff has similarly failed to respond to Defendant's contention that her Section 1983 claims for damages are barred by sovereign immunity. Plaintiff thus abandons those claims, and they should be dismissed as well.

# II. Federal Law Does Not Preempt the School Mask Rule

The DOH showed in its moving papers that Plaintiff's Supremacy Clause preemption claim is unavailing because she has no private right of action to bring it, and, in any event, it is substantively meritless. DOH Mem. at 13-15. In her opposition brief, Plaintiff merely rehashes the same flawed arguments that the Court rejected in denying her preliminary injunction motion.

Plaintiff does not claim that she can privately enforce the Supremacy Clause, rather, she would infer a private right of action from within the FDCA's informed consent provision, *i.e.*, 21 U.S.C. § 360bbb-3(e)(1)(A)(ii). Opp. at 23, 29. But this ignores binding precedent which establishes that an individual cannot enforce "alleged violations of the FDCA" because "no such private right of action exists" under the Act. *PDK Labs v. Friedlander*, 103 F.3d 1105, 1113 (2d Cir. 1997). Plaintiff similarly ignores the recent court decisions uniformly holding that there is no private right of action under the informed consent provision that she invokes, including the Court's decision in this case. *See* PI Decision at 48; DOH Mem. at 13-14 (citing cases); *Bare v. Cardinal Health, Inc.*, 2022 WL 702593, at \*4 n.2 (E.D. Tenn. Mar. 8, 2022) (finding that the informed consent provision did not provide a private right of action to plaintiff challenging COVID-19 vaccine mandate); *Crosby v. Austin*, 2022 WL 603784, at \*1 (M.D. Fla. March 1, 2022) (same). Plaintiff cites nothing to the contrary, and her preemption claim fails at the outset.<sup>3</sup>

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<sup>&</sup>lt;sup>3</sup> Plaintiff also errs in claiming that legislative history and agency interpretations "show" an "inten[t] to provide" a private right of action. Opp. at 23. The congressional speeches and FDA guidance she cites (Opp. at 26-29) do not mention private enforcement of the FDCA, nor could they override the Act's express language precluding a private right. 21 U.S.C. § 337(a) ("all such proceedings for the enforcement . . . of [the FDCA] shall be by and in the name of the United States").

In any event, the School Mask Rule cannot conflict with an EUA on cloth masks for the public because there are plenty of masks children can wear—such as surgical and N95 masks—that are not subject to any EUA. Plaintiff concedes the point. Opp. at 6 (N95 masks for children not authorized by EUA).<sup>4</sup> Whether or not the FDA has issued an EUA for cloth, surgical, or N95 masks for the general public is not a "contested fact" as Plaintiff claims. Opp. at 23. EUAs are public records whose content is not subject to reasonable dispute, and the mask EUAs are referenced in the Amended Complaint. Am. Compl. ¶¶ 162-69, 226. The Court should take judicial notice of the EUAs, and dismiss Plaintiff's preemption claim because the Rule does not require students to wear any mask subject to an EUA. DOH Mem. at 4 n.1, 11 (citing cases); see also Apotex Inc. v. Acorda Therapeutics, Inc., 823 F.3d 51, 59-60 (2d Cir. 2016) (taking judicial notice of publicly available FDA guidance that could not be reasonably questioned).

Moreover, Plaintiff fails to respond to—and therefore concedes—DOH's contention that the School Mask Rule does not violate the informed consent provision because it does not require the wearing of masks under criminal or civil monetary penalty. DOH Mem. at 15. On this basis, courts have repeatedly rejected challenges to laws that condition entry into a business or school on an individual being vaccinated against COVID-19. *Id.* (citing cases) *Dixon v. De Blasio*, 2021 WL 4750187, at \*13 (E.D.N.Y. Oct. 12, 2021) (Cogan, J) (rejecting claims that city orders requiring that individuals receive COVID-19 vaccines to remain in "covered premises" violated informed consent provision because the orders "are not a mandate" and "do not criminalize an individual's choice to refuse a vaccine"), *vacated and remanded on other* 

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<sup>&</sup>lt;sup>4</sup> While the FDA has stated that N95 masks were not designed for children, its concern is that they "may not provide full protection" from disease, not that they are useless or dangerous for children <a href="https://www.fda.gov/medical-devices/personal-protective-equipment-infection-control/n95-respirators-surgical-masks-face-masks-and-barrier-face-coverings">https://www.fda.gov/medical-devices/personal-protective-equipment-infection-control/n95-respirators-surgical-masks-face-masks-and-barrier-face-coverings</a> (last visited May 12, 2022). Regardless, neither the FDA nor CDC have recommended against children using surgical masks, which are not subject to any EUA.

grounds, 2022 WL 961191 (2d Cir. Mar. 28, 2022). A requirement conditioning entry into a school on wearing a removable mask is clearly less invasive than a vaccine requirement, and thus should be upheld *a fortiorari*.<sup>5</sup>

In sum, Plaintiff's preemption claims fail for all of the above independent reasons.

### III. Plaintiff's Substantive Due Process Claims Are Meritless

The essential point missed by Plaintiff is that the Courts have consistently upheld mask mandates because they do not implicate any fundamental rights. DOH Mem. at 15-17. Plaintiff entirely ignores this wealth of case law—including the Court's decision in this action that she lacks a fundamental right to refuse masking—and she does not cite a single case to the contrary. Plaintiff's silence speaks volumes, and her substantive due process claims should be dismissed on the basis of this overwhelming precedent. However, in an abundance of caution, DOH responds to Plaintiff's arguments concerning each of her purported fundamental rights.

### A. Plaintiff's Alleged Right to a Medical Exemption

Plaintiff erroneously claims that she has a fundamental right to obtain a medical exemption from every public health mandate. Opp. at 9-12. To conjure up such a broad right, however, Plaintiff relies solely on cases decided in the abortion context. As this Court has held, abortion involves a decision that is "intimate and personal," and thus is entirely dissimilar from a measure taken to protect the public health that would be undermined if many people could easily avoid it by obtaining exemptions. PI Decision at 42 (no "standalone fundamental right" to a medical exemption requested by a personal physician).

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<sup>&</sup>lt;sup>5</sup> Plaintiff's remaining arguments are equally meritless. DOH has not claimed that it could satisfy the informed consent provision by alerting individuals subject to the Rule "that they may be coerced to accept" a mask against their will. Opp. at 26; *id.* at 24-26. Rather, the informed consent provision simply does not apply here. Similarly, Plaintiff's references to the FDCA's express preemption clause are of no moment because such provision does not conflict with the School Mask Rule for the reasons discussed above.

But even if there were a fundamental right to a medical exemption, the School Mask Rule would plainly not infringe upon it because the Rule <u>permits</u> exemptions for those who cannot medically tolerate a mask. ECF No. 53 Exs. B, D, E. Contrary to Plaintiff's claims (Opp. at 9), the Rule is consistent with *Jacobson* because a person would be exempt if he "had a condition of his health or body" that would make following "the act" "cruel and inhuman in the last degree." *Jacobson v. Mass.*, 197 U.S. 11, 38-39 (1905). Nor is it comparable to the partial birth abortion ban struck down in in *Sternberg v. Carhart*, 530 U.S. 914 (2000), or the parental notification requirement at issue in *Ayotte v. Planned Parenthood of N. New England*, 546 U.S. 320 (2006), because those restrictions <u>did not</u> allow exceptions that would protect the health of the mother.

Indeed, based on her alleged disability Plaintiff already has requested—and received—a reasonable accommodation under the School Mask Rule. Am. Compl. ¶ 214. Her attack on the Rule for purportedly failing to permit medical exemptions should be rejected as meritless.

# B. Plaintiff's Alleged Right to Refuse the "Medical Intervention" of Masking

Plaintiff claims that she has a fundamental right to refuse a mask because it is an "experimental medical product." Opp. at 12-14. But a mask is not even medical treatment, let alone an experimental device. *See* DOH Mem. at 18-19. As this Court found, the School Mask Rule "no more requires 'medical treatment' than laws requiring shoes in public places, or helmets while riding a motorcycle." PI Decision at 43 (citation omitted); *see also Gunter v. N. Wasco Ctyu. Sch. Dist.*, 2021 WL 6063672, at \*9 (D. Or. Dec. 22, 2021) (dismissing challenge to school mask mandate and relying on this language from PI Decision). Plaintiff requests the Court

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<sup>&</sup>lt;sup>6</sup> Plaintiff also relies on *Planned Parenthood of Se. Pennsylvania v. Casey*, 505 U.S. 833, 879 (1992), but that case upheld the scope of a statutory medical exemption, which—like the one here—adequately protected the health of individuals within its ambit.

reconsider this common-sense holding, but the time for her to move for reconsideration has long passed. *See* E.D.N.Y. Local Rule 6.3.

Even if wearing a mask constituted medical treatment, Plaintiff's claim would still fail because it is clearly not an experimental treatment that could infringe on Plaintiff's fundamental rights. "The Mask Mandate is not an experiment or clinical trial; it is a school safety measure." PI Decision at 48. This case is obviously distinguishable from those which Plaintiff relies upon involving dangerous medical experiments, like *Abdullahi v. Pfizer, Inc.*, 562 F.3d 163, 183-84 (2d Cir. 2009). There, Nigerian schoolchildren alleged that a pharmaceutical company tested an experimental drug on them without informing their parents of alternative treatments or potential side effects. Plaintiffs claimed that the drugs caused the death of eleven children and left others blind, deaf, or paralyzed. *Id.* at 168-69. Here, Plaintiff of course does not (and cannot) allege that the same kinds of horrific injuries or deaths result from wearing a removable mask. Nor does she claim that parents have no alternative to compliance with the School Mask Rule. Parents may choose to keep their children from attending school if they refuse to let their child wear a mask without a valid exemption. For these reasons, Plaintiff fails to state a claim that DOH violated any fundamental right to refuse "experimental" medical treatment.

# C. <u>Plaintiff's Alleged Right to Override Public Health Measures Based on Guidance from Her Personal Physician</u>

Plaintiff also claims that she has a fundamental right to let her personal medical provider determine whether she and her child must comply with the School Mask Rule. She again relies on cases concerning the scope of medical exemptions to abortion restrictions (Opp. at 16-18), which are off the point for the same reasons noted above. Abortion is a private health decision, while the School Mask Rule is a public heath measure taken to reduce the spread of a deadly and

highly contagious disease.<sup>7</sup> Plaintiff cites no case directly supporting her novel argument that schools must defer to private medical providers in enforcing a public health mandate. And this Court has ruled otherwise, stating that it is the government that should review medical exemptions because it can best weigh the competing health concerns of the individual student against "everyone else present in the classroom," unlike a personal physician who is "ill-equipped" to do so. PI Decision at 42.

Even if Plaintiff had the right she claims (and she does not), the School Mask Rule would not violate it because the consequence of failing to comply with the Rule is being barred from school; not a criminal or civil penalty. Plaintiff entirely ignores *Doe v. Zucker*, 520 F. Supp. 3d 217 (N.D.N.Y. Feb. 17, 2021), cited in DOH's moving brief, which is directly on point. There, the court held that the conditions for obtaining a medical exemption from vaccination requirements did not violate parents' fundamental rights even if children may be barred from attending school. The court reasoned that "the decision to vaccinate remains with the child's physician and the parent" regardless of any exclusion from school. *Id.* at 253. So too here.

In response, Plaintiff cites *W. Virginia State Bd. of Educ. v. Barnette*, 319 U.S. 624 (1943), where the Supreme Court struck down a board of education resolution requiring students to salute the flag. Opp. at 18-19. *Barnette* is manifestly distinguishable from the case at bar. First, the penalty for failing to salute the flag was not only removal of the child from school, but also the potential prosecution of the parents. *Barnette*, 319 U.S. at 629. There is no risk of that

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<sup>&</sup>lt;sup>7</sup> Plaintiff claims that in *Whalen v. Roe*, 429 U.S. 589 (1977), the Supreme Court extended the alleged right to obtain a health exemption based on a doctor's request outside of the abortion context. In *Whalen*, the Court upheld a New York law requiring physicians to inform the government about patients to whom they prescribed controlled substances. *Id.* at 591. In doing so, the Court noted that the law did not deprive anyone "of the right to independently, with the advice of his physician . . . acquire and . . . use needed medication." *Id.* at 603. However, this Court aptly found that *Whalen* was unhelpful to Plaintiff—observing that it actually permitted the government to enforce significant restrictions on the physician/patient relationship, including limiting medication doses and even allowing outright bans. PI Decision at 42 n.23; *Whalen*, 429 U.S. at 603.

here. Second, those students who chose not to salute the flag did not risk harming others. "[T]he power of compulsion is invoked without any allegation that remaining passive during a flag salute ritual creates a clear and present danger." *Id.* at 633-34. That clearly differs from a rule requiring masks to contain the spread of a highly transmissible disease. Third, the resolution in *Barnette* regulated speech and thus received greater scrutiny under the First Amendment than the one challenged here under the Fourteenth Amendment. An ordinary State regulation will survive if "a legislature [has] a 'rational basis for adopting [it]. But freedoms of speech and of press, of assembly, and of worship may not be infringed on such slender grounds." *Id.* at 639. As Plaintiff does not claim an infringement on her right to free speech, *Barnette* is inapposite. The potential exclusion of Plaintiff's daughter from school for refusing to wear a mask absent a valid medical exemption simply does not give rise to a constitutional violation.<sup>8</sup>

### D. The School Mask Rule Easily Passes Rational Basis Review

Plaintiff does not argue that the School Mask Rule itself is irrational, only that the District has applied it in an irrational manner. Opp. at 22. In any event, the State Defendant's Rule requiring masking in public spaces to prevent transmission of a deadly disease should be upheld because it is plainly rational. DOH Mem. at 21-22 (citing cases).

The DOH could—but need not—rely on the *Jacobson* standard upholding measures that have a "real or substantial relation' to public health," because the School Mask Rule survives more rigorous rational basis review. 197 U.S. at 31. Nonetheless, Plaintiff challenges *Jacobson* claiming that the Supreme Court "overturned" the decision in *Roman Catholic Diocese* v. *Cuomo*, 141 S. Ct. 63 (2020) ("*Diocese*"). Opp. at 20. But the *Diocese* court did not even

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<sup>&</sup>lt;sup>8</sup> Plaintiff also erroneously cites *Barnette* to claim that the School Mask Rule violates the "unconstitutional conditions" doctrine because New York allegedly conditions the benefit of education on Plaintiff giving up her right not to wear a mask. But as made clear in DOH's moving brief and in this one, Plaintiff does not have a fundamental right to not wear a mask, and thus her ancillary "unconstitutional conditions" argument fails. DOH Mem. at 20 n.39.

mention *Jacobson*, let alone overrule it. Plaintiff next claims that the Second Circuit's decision upholding the plaintiffs' free exercise challenge in *Agudath Israel v. Cuomo*, 983 F.3d 620, 635 (2d Cir. 2020), called *Jacobson* into question even in actions where free exercise claims are not at issue. Courts, however, have repeatedly applied *Jacobson* to dismiss 14th Amendment challenges to public health mandates post *Diocese* and *Agudath Israel*. *See, e.g, Hopkins Hawley, LLC v. Cuomo*, 518 F. Supp. 3d 705 (S.D.N.Y. Feb. 9, 2021) (considering in detail whether *Jacobson* has been abrogated by *Diocese* and *Agudath Israel*, and concluding, with respect to plaintiffs' substantive due process claims, that "Jacobson's deferential standard of judicial review is still applicable"). Finally, Plaintiff relies on concurring opinions from four Supreme Court justices in *S. Bay United Pentecostal Church v. Newson*, 141 S. Ct. 716 (2021). But, like the *Diocese* decision, those concurrences do not mention *Jacobson* and, in any event, they are not binding. *See Maryland v. Wilson*, 519 U.S. 408, 412-13 (1997) (justice's concurrence does not "constitute[] binding precedent").

In sum, the *Jacobson* standard applies in this case and the School Mask Rule easily meets that standard (DOH Mem. at 22 n.41), just as it survives rational basis scrutiny.

### IV. Plaintiff's Disability Discrimination Claims Against DOH Are Unavailing

In her opposition brief, Plaintiff concedes that the School Mask Rule permits reasonable accommodations for individuals under federal disabilities law. *See* Opp. at 2-3 (quoting relevant portions of Rule); *id.* at 7 ("[t]he [Mask] Mandate itself contemplates and requires exemptions"). She makes the same concessions in her pleading: "Plaintiff has requested the accommodation of not wearing a mask in school, an accommodation available to her under the NYSDOH temporary orders [the School Mask Rule]." Am. Compl. ¶ 282. While Plaintiff claims elsewhere in her brief that the Court found this issue "confusing," that is simply not the case. In fact, the Court found in

no uncertain terms that under the School Mask Rule, "school districts must always comply with the ADA." PI Decision at 15.

Plaintiff is left to argue that DOH had a role in denying her daughter's request for a reasonable accommodation. Opp. at 30. But the Rule itself undermines this claim. DOH does not review requests for exemptions from the Rule or decisions on such requests. *See* ECF No. 53, Exs. B, D, E. Plaintiff's argument is also contradicted by her own pleading: "DOH "do[es] not have a policy of reviewing or denying mask exemption requests." Am. Compl. ¶ 49. And Plaintiff similarly errs in claiming that DOH has discriminated against "categories" of disabled children. Opp. at 30. Given that DOH does not consider individual exemption requests under the Rule, it certainly does not review—let alone universally deny—exemption requests from groups of children. Moreover, as this claim appears nowhere in the Amended Complaint, it should be rejected on that basis as well. "Plaintiffs 'should not be able effectively to amend a complaint through any document short of an amended pleading." *Doe v. Merck & Co.*, 803 F. App'x 559, 560 n.3 (2d Cir.), *cert. denied*, 141 S. Ct. 900 (2020).9

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<sup>&</sup>lt;sup>9</sup> Thus, Plaintiff's reliance on a court transcript to supplement her allegations is improper. Opp. at 17, 30-31. In any event, DOH counsel's statements at the October 15, 2021 court conference about the effect of CDC guidance on this case hardly, as Plaintiff claims, show that the School Mask Rule is vague as to whether it permits exemptions for disabled individuals who cannot tolerate a mask. The Rule clearly does permit such exemptions. *See* PI Decision at 15. As Plaintiff had not asserted a claim under the disability statutes at that time and "reasonable accommodations" were not yet a disputed issue, counsel was not fully cognizant of the individualized assessment school districts must make. *See* DOH Mem. at 25 (describing assessment process).

### **Conclusion**

For all of the foregoing reasons, DOH's motion to dismiss should be granted and the Amended Complaint dismissed in its entirety and with prejudice as against the State Defendant.

Dated: New York, New York May 12, 2022

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